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RECORD OF ORAL HEARING
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GARY E. BORODIC

Appeal 2008-2452
Application 09/382,837
Technology Center 1600

Oral Hearing Held: August 13, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANT:

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PROCEEDINGS

MS. BEAN: Calendar Number 12, Mr. Longton.

JUDGE ADAMS: Thanks, Lisa.

Good morning, Mr. Longton.

MR. LONGTON: Good morning.

JUDGE ADAMS: We're familiar with your issues. You'll have 20 minutes, and if you'll begin by introducing your colleagues and spelling your name into the record we'd appreciate it.

MR. LONGTON: All right. May it please the Court, my name is Rick Longton, representing the Applicant, Dr. Gary Borodic. with me today are my colleagues, Stephanie Ameroso (phonetic sp.) and Sohe Choy (phonetic sp.).

JUDGE ADAMS: And if you'd spell your name into the record for us.

MR. LONGTON: My first name is Enrique, E N R I Q U E, last name L O N G T O N.

JUDGE ADAMS: Please.

MR. LONGTON: The claimed invention today that we're about is based on the discovery by Dr. Borodic that inflammatory disorders may be treated using dosages of Botulinum toxin well below the amounts used to induce muscle weakness.

This is a break-through discovery as evidenced by the fact of the 26 pending claims. Only three stand rejected over references in a 103 rejection. Now, the Examiner's answer sets forth three bases for rejecting the pending claims: there's a written description rejection, there's an enablement rejection and there's an obviousness rejection.

It's our position, the Applicant's position, that the Examiner has misapplied the law of written description, enablement, and obviousness.

Turning first to written description, it seems to be that the Examiner's position is based on a reading of the disclosure that doesn't take into account the Applicant's teaching as a whole. This is contrary to what the inventive process is all about. Rather, the Examiner takes each word and sentence in the disclosure as an isolated statement that can't be combined with any other teachings and disclosure.

It's Applicant's position that this is entirely improper and should be reversed.

JUDGE ADAMS: Okay.

JUDGE FREDMAN: Wouldn't you say, just for example, at page 5 your Specification talks about reducing inflammation by using the agent? Then you later talk about the minimum effective doses. Then you give specific doses that are much lower than the normal which pretty much is the claim that the Examiner says isn't there. I mean, it's pretty much disclosed by pages 5 and 6 of your spec.

MR. LONGTON: That's, that's our position, though. We disclosed everything and, frankly, we can't figure why the Examiner has taken this position. It's all there.

JUDGE ADAMS: So, just so we're clear, the written description rejection is almost a new matter rejection, right, where you added this subject matter to the end of your claim that would recite that less than a dose necessary to produce a substantial muscle weakness and within the affected area?

MR. LONGTON: I --

JUDGE ADAMS: That sort of the idea?

MR. LONGTON: I'm not sure where he's coming from --

JUDGE ADAMS: Right.

MR. LONGTON: -- to tell you the truth.

JUDGE ADAMS: But it seems that -- it seems from at least my reading that his, his, his concern is that there's not a disclosure of that last clause of your claim.

MR. LONGTON: Of the dose less than amount to --

JUDGE ADAMS: For reduced -- right. Where you're reducing it you -- where you have a method of reducing inflammation wherein you're administering an effective dose that is less than that dose necessary to produce substantial muscle weakness.

MR. LONGTON: Well, I -- no, I think that's really throughout the Specification.

JUDGE ADAMS: Right. For example, at, at page 4 of your spec you talk about the use of toxin at one-third to serve an order of magnitudes less than that associated with regional muscle movement diseases. Is that right?

MR. LONGTON: Um-hum.

JUDGE ADAMS: Now, regional treatment of regional muscle -- excuse me, treatment of regional movement diseases that would be that treatment that produces substantial muscle weakness. Is that the idea?

MR. LONGTON: That's right. That's the movement disorders are treated by inducing muscle weakness.

JUDGE ADAMS: And then if you would look for me at page 5 of the spec.

MR. LONGTON: Um-hum.

JUDGE ADAMS: At the first indented paragraph.

MR. LONGTON: Um-hum.

JUDGE ADAMS: It is a finding of the subject invention that pharmaceuticals such as Botox or Botulinum toxin in low dosages are effective anti-inflammatory agents typical minimum effective dosages range from .5 to 5 units as opposed to 20 to 500 units for the treatment of movement disorders.

MR. LONGTON: Right.

JUDGE ADAMS: So that, in your opinion, would be something that would suggest that you're administering something less than that if it is necessary to produce a substantial muscle weakness.

MR. LONGTON: Yes, and we actually specifically say muscle less than the amount required for muscle weakness. Actually, I think it's an original claim in 1. I can't find it right now.

JUDGE ADAMS: Well, original Claim 1 would say a method of using --

JUDGE FREDMAN: You're looking at 2.

JUDGE ADAMS: -- inflammation comprising the step of administering a chemo denervating agent to an anatomic region.

JUDGE FREDMAN: Claim 2. You're looking at 2.

JUDGE ADAMS: Original Claim 2 would suggest a method of treating inflammation comprising the step of administering a chemo denervating agent to an anatomic region in a dose just sufficient to reduce inflammation but below that necessary to cause substantial muscle weakness.

MR. LONGTON: Right, that's originally filed Claim 2.

JUDGE ADAMS: Okay.

MR. LONGTON: And, then on page 19 of the Specification, we say minimum dosages range from between .6 units to 15 units and are far lower than that required to produce regional weakness.

JUDGE ADAMS: So, what's the Examiner's enablement rejection?

MR. LONGTON: The Enablement Rejection seems to be based on his assertion that there are not enough examples provided in the Specification. And, that's another instance where we just don't understand where he's coming from because we provide 14 pages of examples exemplifying 7 different conditions that have been treated.

We, we talk about Rheumatoid Arthritis, Spasmodic Torticollis on page 17, Internal Inflammatory Diseases --

JUDGE ADAMS: But, isn't it the Examiner's position that in each one of those examples you're not using a dosage that's, that is less than that that would be required to induce --

MR. LONGTON: Well --

JUDGE ADAMS: -- substantial muscle weakness.

MR. LONGTON: His, his -- if that's his position, that's incorrect because if you looked specifically at the allergic blepharoconjunctivitis example on page 15 --

JUDGE ADAMS: Well, he would say that that's your only example that would suggest doing it with a, with a dosage that is less than that that would produce --

MR. LONGTON: Well that's--

JUDGE ADAMS: -- substantial muscle weakness and therefore I believe he's saying you're only enabled for that. You're only enabled for a method of reducing inflammation without causing -- wait, where is it?

That you're enabled for a method for reducing allergy induced conjunctivitis in amounts comprising of administering a Botulinum toxin. That's at page 5 of the Examiner's answer.

MR. LONGTON: Well, that's -- respectfully, that's, that's ignoring the example of the UTICARIA on pages 10 to 13. I mean, that, that's a classic example of inflammation.

JUDGE ADAMS: And, that's, that's using a dosage that's less than that that would be required.

MR. LONGTON: Yes, Your Honor, that's at I think it was 2.5 units and he dismisses that without providing any reason.

JUDGE ADAMS: What page was that?

JUDGE FREDMAN: Page 113 --

MR. LONGTON: UTICARIA is at pages 10 to 13. There are two case studies.

JUDGE ADAMS: According, according to the Examiner's Answer, he would say that regarding the Spasmodic -- I'm sorry.

MR. LONGTON: Spasmodic Torticollis.

JUDGE ADAMS: Thank you. It is noted that the example does not actually disclose that any specific dosage of any specific toxin results in any specific outcome. That's at page 7 in the answer.

MR. LONGTON: Well, no that's, that's where we come back to this idea that he's not reading the Specification as a whole. The Specification of

a whole, as a whole when you read it in its entirety talks about these low doses that are used and are contemplated specifically in the invention.

His position seems to be that we, we don't exemplify specific treatments and therefore are not entitled to the scope of the claims, and that's just not the law. No examples are required.

JUDGE ADAMS: Okay. And, your position with regard to the prior art rejection?

MR. LONGTON: The obviousness rejection is over Claims 10 to 12. The Examiner acknowledges in his rejection that the Primary Reference, the 768 Patent, doesn't teach a method of reducing inflammation due to blepharoconjunctivitis, hay fever, rhinitis or type 1 hypersensitivity. He also acknowledges that the patent doesn't teach the use of other anti-inflammatory agents comprising steroids or non-steroids.

And, his Secondary Reference doesn't cure these deficiencies; specifically the Merck Manual. First of all, it's a general reference sort of like an encyclopedia. It doesn't teach or suggest or even motivate using a toxic protein which is Botulinum toxin for the treatment of inflammation. It doesn't teach specific limitations. If you look at Claim 10 that's directed to allergic blepharoconjunctivitis that's nowhere in any of their references. There's no teaching of hay fever.

JUDGE ADAMS: Well, my question would be what does First teach?

MR. LONGTON: First --

JUDGE ADAMS: This, this patent that the Examiner relies on. What's it all about?

MR. LONGTON: My reading of First is it's a general reference directed to the use of Botulinum toxin for a few inflammatory disorders.

JUDGE ADAMS: Is there any allergic inflammatory disorders disclosed in First?

MR. LONGTON: Not that I am aware of, Your Honor.

JUDGE ADAMS: What is this, this neurogenic disorder? Is there any relationship between that and an allergic disorder?

MR. LONGTON: I don't know.

JUDGE ADAMS: Okay. Well, we're getting to the nexus between First and these disorders that are disclosed in Merck; right? So, if, if First talks about a whole bunch of types of disorders - these neurogenic disorders, discloses a variety of the types of disorders encompassed by that on Column, on Column 6. And, then we move off to Merck which talks generally about allergic disorders and I think the Examiner's position would be, well we know that you can use Botulinum toxin to reduce inflammation so we would combine that with a steroid or non-steroidal anti-inflammatory as taught by Merck for the sake of combining them. Is that the idea?

MR. LONGTON: No, I think his rejection fails, number one, because you have to have the limitations there, and he doesn't have limitations.

JUDGE ADAMS: Um-hum.

MR. LONGTON: Specifically the allergic blepharoconjunctivitis. That's a specific requirement of Claim 10. Number two, Merck fails because there's no suggestion of using a toxic protein like Botulinum toxin. There's no reason to modify Merck or modify First using Merck.

JUDGE ADAMS: Why not?

MR. LONGTON: Because Merck is a general reference that lacks the limitations of Claim 10, for example. Also, the limitations --

JUDGE ADAMS: Merck says anti-inflammatories are useful for treating allergic inflammation. Is that right?

MR. LONGTON: I'm sorry?

JUDGE ADAMS: Does Merck suggest the use of anti-inflammatory agents to treat allergic inflammation?

MR. LONGTON: It teaches -- Merck, Merck says that you can use anti-inflammatory agents to treat inflammatory diseases.

JUDGE ADAMS: Okay.

MR. LONGTON: But, it doesn't go anywhere near toxic proteins or Botulinum toxin.

JUDGE ADAMS: And, First would say use Botulinum toxin to treat these types of inflammatory diseases.

MR. LONGTON: Only a certain subset of, of inflammatory diseases.

JUDGE FREDMAN: Do you see any distinction between Claims 10 and 11, and I guess 12 as well where 10 is a specific allergic blepharoconjunctivitis, 11 is classic type 1 hypersensitivity. It seems somewhat broader.

MR. LONGTON: My understanding that those are different classes of inflammatory diseases. So, I think the distinction is a clinical distinction. And, that's my best understanding.

JUDGE ADAMS: So, both First and Merck would suggest using anti-inflammatories to treat inflammatory disorders. Is that right?

MR. LONGTON: First suggests using Botulinum toxin.

JUDGE ADAMS: As an anti-inflammatory.

MR. LONGTON: Well, I don't know what the mechanism is. It's, it says use Botulinum toxin to treat these neurogenic disorders.

JUDGE ADAMS: Which are inflammatory disorders.

MR. LONGTON: As far as I know.

JUDGE ADAMS: Okay, so then the Botulinum toxin would be an anti-inflammatory as far as you know.

MR. LONGTON: Yeah.

JUDGE ADAMS: Okay. So both First and Merck suggest using anti-inflammatories to treat inflammatory disorders; right?

MR. LONGTON: Yes.

JUDGE ADAMS: So, why wouldn't you use Botulinum toxin as an anti-inflammatory according to Merck?

MR. LONGTON: Because Merck doesn't teach the specific inflammatory diseases that we're claiming.

JUDGE ADAMS: Well, it's not an -- excuse me, it's not an anticipation rejection.

MR. LONGTON: But --

JUDGE ADAMS: It's an obviousness rejection.

MR. LONGTON: But, even in an obviousness --

JUDGE ADAMS: Wouldn't it be obvious to use Botox, Botulinum toxin, according to First in the, in the methodology taught by or suggested by Merck?

MR. LONGTON: Possibly as a genus, but we are claiming a specific species of inflammatory disorders. And, even in a 103 rejection, you have to have all of the limitations present in the prior art.

JUDGE ADAMS: So, so your argument would be that the Examiner hasn't made a connection between the disorders taught by First and those taught by Merck; right?

MR. LONGTON: Right. He's, he's not established a prima facie case. He doesn't have the limitations.

JUDGE ADAMS: Alright. Any further questions? Any further questions? Unless you have anything further we're good.

MR. LONGTON: No, I just I, I'd just like to reiterate that the Examiner in his written description and enablement rejections are just hard to fathom. I mean, we have completely described and provided in our Brief exactly where support can be provided for all of the limitations in the claims and he's ignored, in our view, that aspect of the Brief. And, the same for the enablement rejection.

JUDGE ADAMS: Okay, thank you.

MR. LONGTON: Thanks.

(Whereupon, the hearing concluded at 9:58 a.m. on August 13, 2008.)